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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHRISTOPHER T. BOYLE

Appeal 2010-007338
Application 09/716,146
Technology Center 3700

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 16, 20, 26-28, and 30-37, directed to an endoluminal stent. The claims have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

Claims 16, 20, 26-28, and 30-37 are pending and on appeal. Claim 16 is representative of the subject matter on appeal:

16. An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of vacuum deposited structural elements forming a radially expandable cylindrical member, the plurality of structural vacuum deposited elements including a complex finished geometry, each of the plurality of vacuum deposited structural elements having a wall thickness; wherein the vacuum deposited structural elements are fabricated of a metal and comprise a base layer and a second layer covering the base layer, further comprising a void space intermediate the base and second layers that is enclosed therebetween;

a plurality of pores passing through the second layer and communicating with the void space such that the void space is open only through the plurality of pores; and

at least one bioactive agent retained within the void space and elutable through the plurality of pores.

The Examiner rejected claims 16, 20, 26-28, and 30-37 under 35 U.S.C. § 103(a) as unpatentable over Brown (US 6,071,305, June 6, 2000) and Whicher (US 6,938,668 B2, September 6, 2005).

We reverse.

FINDINGS OF FACT

The present Specification

1. Claim 16, the only independent claim, is directed to a radially expandable endoluminal stent made up of a plurality of vacuum deposited structural elements, where the structural elements "are fabricated of a metal and comprise a base layer and a second layer covering the base layer," with void space between the base and second layers, and pores in the second layer communicating with the void space. The void space contains a bioactive agent, which is elutable through the pores.

2. According to the Specification, the stents are "preferably formed of a metal such as titanium . . . or stainless steel" (Spec. 8: 23-26), and "forming wrought metal parts, such as capillary tubing, into the implantable device or forming the implantable devices by vacuum deposition techniques . . . [is] the preferred method of making the implantable structural elements" of the stents (*id.* at 10: 18-20).

3. "Where an implantable device is to be formed from non-preexisting structural elements, vacuum deposition techniques may be employed to form the implantable structural body" (Spec. 11: 2-4). Internal cavities and openings can be formed by depositing patterned sacrificial material "over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer" and removing the sacrificial material "to leave the internal cavities and plurality of openings formed within the deposited bulk material" (*id.* at 11: 10-13).

4. Alternatively, "[w]here an implantable device is to be fabricated of a plurality of individual tubular elements, such as depicted in Figures 5-7," the Specification teaches that "pre-existing microtubular members . . . may be employed" (Spec. 10: 20-23), and "openings passing through the wall of each of the individual tubular elements may be formed by microdrilling the openings through the wall and into the internal cavity or lumen of the individual tubular members" (*id.* at 10: 29-31).

5. Figures 1-7 of the Specification, reproduced immediately below, depict various alternative embodiments of implantable endoluminal stents:

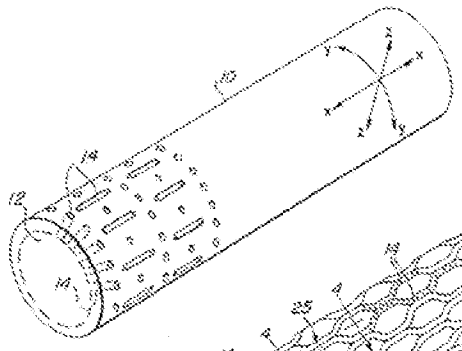


Fig. 1

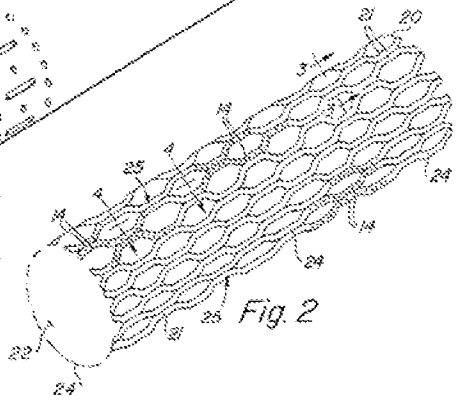


Fig. 2

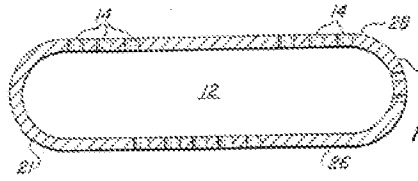


Fig. 3

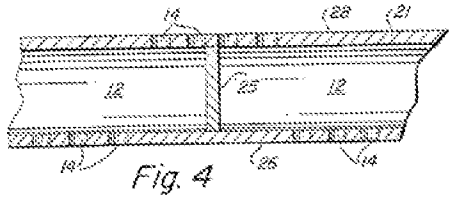


Fig. 4

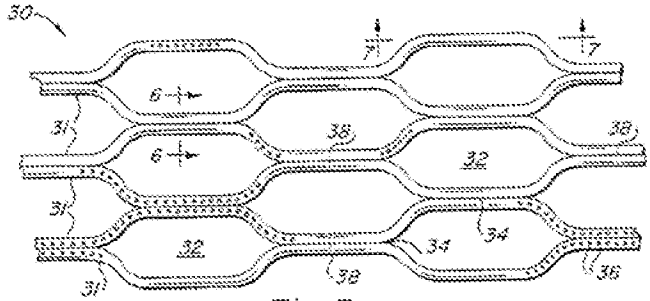


Fig. 5

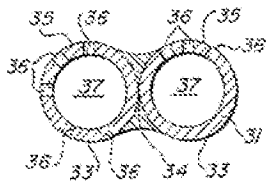


Fig. 6

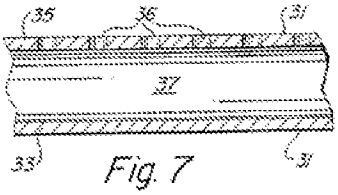


Fig. 7

> Figure 1 is a perspective view of an implantable member in accordance with the present invention.
>
> Figure 2 is a perspective view of an endoluminal stent having a plurality of structural members in accordance with the present invention.
>
> Figure 3 is a cross-sectional view taken along line 3-3 of Figure 2.
>
> Figure 4 is a cross-sectional view taken along line 4-4 of Figure 2.
>
> Figure 5 is a fragmentary perspective view of an alternative embodiment of the inventive endoluminal stent in accordance with the present invention.
>
> Figure 6 is a cross-sectional view taken along line 6-6 of Figure 5.
>
> Figure 7 is a cross-sectional view taken along line 7-7 of Figure 5.

(Spec. 5: 21-30.)

According to the Specification, "[e]ach of the tubular structural elements 31 [shown in Figures 6 and 7] has a central lumen 37 that forms the internal cavity within each structural element 31" and "[e]ach of the tubular structural elements 31 has a plurality of openings 36 which communicate between the internal cavity 37 and one or both of a luminal surface 33 or an abluminal surface 35 of each of the plurality of tubular structural elements 31" (*id.* at 8: 31 to 9: 6).

6. Thus, the present Specification discloses at least two alternative embodiments: one embodiment made up of pre-existing microtubular (i.e., cylindrical) elements, as shown in Figures 5-7, the other embodiment formed by depositing patterned sacrificial material over a vacuum-deposited base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer (*contrast* FF3 and FF4).

Brown

7. Brown describes an expandable drug delivery stent "formed from an elongated or tubular member . . . in the shape of a coil or helix" (Brown, col. 5, ll. 39-42), or "other configurations such as . . . expandable tube stents, roving wire stents, and wire mesh stents. Thus, the elongated member . . . may be the filaments or fibers which form a mesh stent" (*id.* at col. 7, ll. 36-39).

8. Brown's stent is made of a nonbiodegradable material including stainless steel or titanium (Brown, col. 12, ll. 4-7).

9. Brown's Figure 2 is reproduced immediately below:

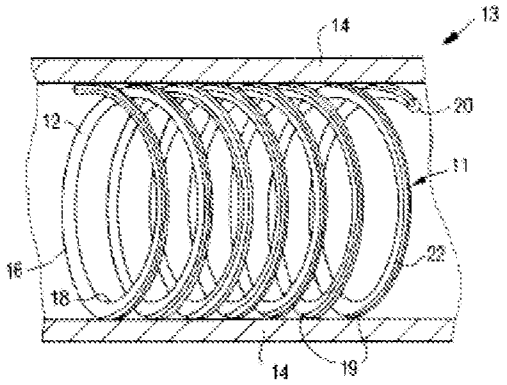


Figure 2 "is a cross sectional side view of a body lumen and a perspective view of a stent" (Brown, col. 3, ll. 62-63), "formed from an elongated or tubular member **12** . . . in the shape of a coil or helix" (Brown, col. 5, ll. 39-42).

10. "The tubular or elongated member **12** of the directional drug delivery stent **11** . . . is formed with an interior or cavity **20** . . . extending along the entire length of the elongated member" (Brown, col. 5, ll. 46-52), and "has a fluid opening or delivery means for directionally delivering a biologically active agent within the cavity or interior **20**" (*id.* at col. 6, ll. 7-9). The fluid opening or delivery means may be "a series or plurality of

holes, grooves, small indentations . . . [or] intermittent recessions" (*id.* at col. 6, ll. 15-16).

11. Brown's Figure 6, reproduced below, "is an enlarged cross-sectional view of the elongated member . . . positioned in a body lumen" (Brown, col. 4, ll. 13-16):

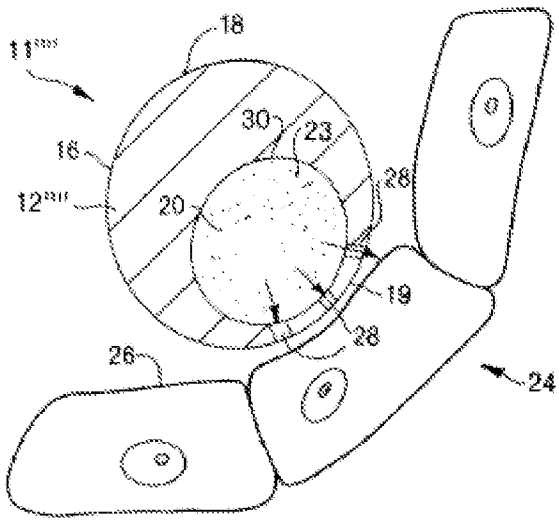


FIG. 6

Figure 6 depicts "an enlarged cross-sectional view of the elongated member . . . positioned in a body lumen" (*id.* at col. 4, ll. 13-16). "[T]ubular member **12''''** of the stent **11''''**, is provided with a plurality of fluid openings or holes **28** . . . [and] [d]irectional delivery of the active agent [**23**] is provided from the cavity **20** through the plurality of holes **28** to the lumen walls **26**" (*id.* at col. 9, ll. 22-30.

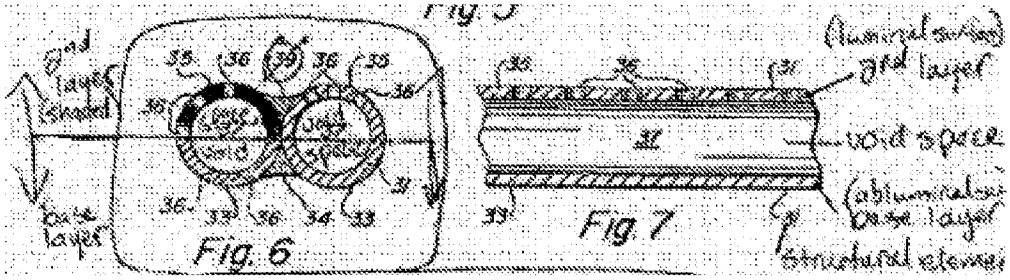
DISCUSSION

The Examiner rejected claims 16, 20, 26-28, and 30-37 as obvious over Brown and Whicher. We will reverse this rejection.

Claim 16, the only independent claim, is directed to a radially expandable endoluminal stent made up of a plurality of vacuum deposited structural elements, made of metal, where the structural elements "comprise

a base layer and a second layer covering the base layer," with void space between the base and second layers, and multiple pores in the second layer communicating with the void space. The void space contains a bioactive agent, which is elutable through the pores.

The Examiner's rejection rests on a finding that "[t]he claims refer to a stent which is shown in appellant[']s figures 2-7, which contains structural elements 21 or 31 shown generally cylindrical, having a longitudinal axis (shown in figure 7) and round transverse cross-section [shown in figure 6]" (Ans. 5). According to the Examiner, "'layers' are not clearly pointed out in the figures" (*id.*), and "it is not clear where one layer starts and ends" (*id.*), thus, "it would *appear* appellant is referring to an abluminal and luminal 'layer'" (*id.*). As re-envisioned and annotated by the Examiner, Appellant's Figures 6 and 7 depict "the second layer . . . shaded to distinguish it from the base layer" (*id.* at 6). The Examiner's annotated version of Appellant's Figures 6 and 7 is reproduced below:



(Ans, Attachment #1 (compare with FF5).)

The Examiner compares Figures 2-7 of the present Specification with Brown's Figures 2a, 3, 6, and 8, and finds that "Brown has shown the same type of structural elements" (Ans. 5), and, "[t]herefore, a 'layer' of appellant's structural element may also be considered a 'layer' of Brown's structural element" (*id.* at 6). Specifically, the Examiner finds that "Brown discloses an endoluminal stent for delivering a bioactive agent . . .

comprising a plurality of structural elements [(12)]" (*id.* at 4), "each structural element (12) . . . comprising a base layer (considered luminal surface or layer 18) and a second layer (considered abluminal surface or layer 19, or vice versa) covering the base layer" (*id.* at 5), with "a void space (20) intermediate the layers and enclosed therebetween, a plurality of pores (22, 28, 54) passing through the second layer (19, or alternatively 18)" (*id.*).

Brown's Figure 6, as re-envisioned and annotated by the Examiner, is reproduced below:

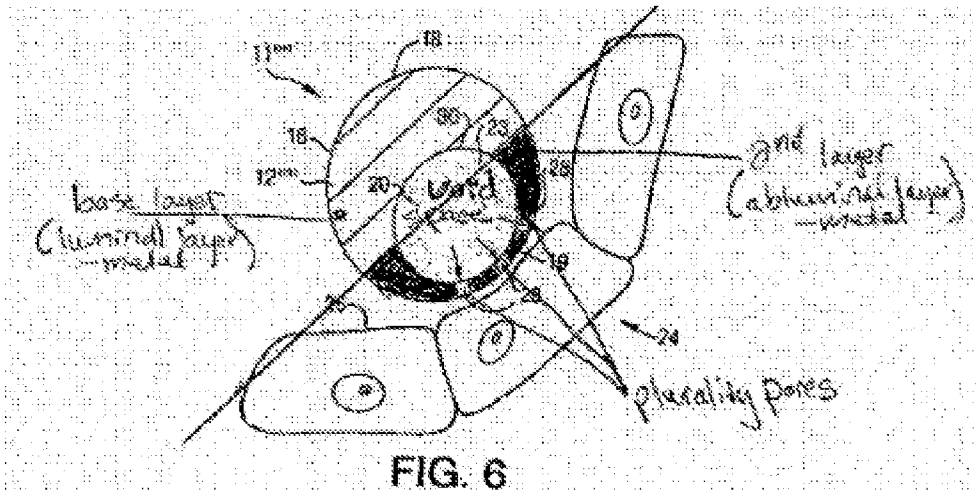


FIG. 6

(Ans., Attachment #3 (compare with FF11).)

Appellant contends that: "Claim 16 requires discrete layers: '**a** base layer and **a** second layer covering the base layer.'" (App. Br. 8). Appellant argues:

> [T]he layers are . . . simply put, separate claim elements of Claim 16. Such a claim construction is necessary to give meaning to the "void space intermediate the base and second layers and enclosed therebetween" limitation. The layers have to be discrete, i.e. apart or detached from each other, in order to have the void space intermediate and enclosed therebetween the second layer and the base layer.

(*Id.* at 8-9.)

Moreover, Appellant contends that the Specification teaches that vacuum deposition techniques may be used to form an implantable device from non-preexisting structural elements, whereby "internal cavities and openings can be formed by depositing patterned sacrificial material 'over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer' and removing the sacrificial material 'to leave the internal cavities and plurality of openings.'" (App. Br. 9). In addition, Appellant points out that claim 16 expressly "requires that the base layer and second layer are 'vacuum deposited structural elements'" (Reply Br. 7).

Appellant argues that "[t]he Examiner's figure by figure comparison of the present application and Brown lends itself to misconstruing the claims and departing from the claim language" (App. Br. 11), and that "[t]he reasonable limits of the meaning of 'layer' are set by the teachings of the present application with reference to the vacuum deposition techniques described in the specification" (*id.*).

We agree with Appellant that the claims plainly require two discrete metal layers - a base layer and a second layer. We also agree with Appellant that Brown's "luminal portion 18 and support portion 19 are portions of a surface and not a base layer and a second layer" (App. Br. 12-13), and that an "arbitrary line draw[n] through [Brown's] helical stent . . . does not transform luminal portion 18 and support portion 19 into a second layer covering the base layer" (*id.* at 13). Similarly, a line drawn through Appellant's Figure 6 does not transform luminal surface 33 and abluminal surface 35 of tubular element 31 into two discrete layers. We know of no authority that requires a structural limitation in the claim to be reconciled, or

otherwise force-fit, to a figure, in order to interpret a structural limitation in the claim that is plain on its face.

Finally, Whicher, cited by the Examiner for its disclosure of "a method of making a stent by vacuum deposition techniques" (Ans. 6), does not make up for Brown's underlying deficiency.

SUMMARY

The rejection of the claims under 35 U.S.C. § 103(a) as unpatentable over Brown and Whicher is reversed.

REVERSED

DM